

United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-------------------------|-----------------------------|--------------------------|-------------------------|------------------|
| 10/764,259 | 01/23/2004 | Oswaldo da Costa e Silva | 16313-0269 | 8334 |
| 29137 7 | 590 10/31/2006 | | EXAMINER | |
| BASF CORP | - | | COLLINS, C | YNTHIA E |
| CARL-BOSCF LUDWIGSHA | I-STRASSE 38 FEN. D67056 | | ART UNIT | PAPER NUMBER |
| GERMANY | , | | 1638 | |
| | | | DATE MAILED: 10/31/2006 | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | Application No. | Applicant(s) | | | | |
|---|---|--|--|--|--|--|--|
| Office Action Summary | | 10/764,259 | SILVA ET AL. | | | | |
| | | Examiner | Art Unit | | | | |
| | | Cynthia Collins | 1638 | | | | |
| | The MAILING DATE of this communication ap | 1 | 1 | | | | |
| Period fo | Period for Reply | | | | | | |
| WHIC - Exter after - If NO - Failu Any r | ORTENED STATUTORY PERIOD FOR REPLICHEVER IS LONGER, FROM THE MAILING Insions of time may be available under the provisions of 37 CFR 1. SIX (6) MONTHS from the mailing date of this communication. Period for reply is specified above, the maximum statutory period re to reply within the set or extended period for reply will, by staturely received by the Office later than three months after the mailined patent term adjustment. See 37 CFR 1.704(b). | DATE OF THIS COMMUNICATION 136(a). In no event, however, may a reply be tin will apply and will expire SIX (6) MONTHS from the, cause the application to become ABANDONE | N. nely filed the mailing date of this communication. D (35 U.S.C. § 133). | | | | |
| Status | | | | | | | |
| 1)🖂 | Responsive to communication(s) filed on 15 A | August 2006. | | | | | |
| 2a)⊠ | This action is FINAL . 2b) Thi | s action is non-final. | | | | | |
| 3) | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is | | | | | | |
| | closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. | | | | | | |
| Dispositi | on of Claims | | | | | | |
| 4)⊠ | 4)⊠ Claim(s) <u>1-7,11,12 and 15-35</u> is/are pending in the application. | | | | | | |
| | 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | | |
| 5)⊠ | 5) Claim(s) <u>1,2,11,12 and 21-28</u> is/are allowed. | | | | | | |
| 6)⊠ | 6) Claim(s) 3-7,15-17,19,20 and 31-35 is/are rejected. | | | | | | |
| 7)🖂 | Claim(s) <u>18,29 and 30</u> is/are objected to. | | | | | | |
| 8)[| 8) Claim(s) are subject to restriction and/or election requirement. | | | | | | |
| Applicati | on Papers | | | | | | |
| 9)☐ The specification is objected to by the Examiner. | | | | | | | |
| 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. | | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). | | | | | | | |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | | |
| Priority u | ınder 35 U.S.C. § 119 | | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: | | | | | | | |
| | 1. Certified copies of the priority documents have been received. | | | | | | |
| 2. Certified copies of the priority documents have been received in Application No | | | | | | | |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). | | | | | | | |
| * See the attached detailed Office action for a list of the certified copies not received. | | | | | | | |
| | | , | | | | | |
| Attachmen | t(s) | | | | | | |
| 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) | | | | | | | |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date Notice of Informal Patent Application | | | | | | | |
| Paper No(s)/Mail Date <u>081506</u> . | | | | | | | |

DETAILED ACTION

The Amendment filed August 15, 2006 has been entered.

Claims 8-10 and 13-14 are cancelled.

Claims 3-7, 15-17 and 19-20 are currently amended.

Claims 21-35 are new.

Claims 1-7, 11-12 and 15-35 are pending.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All previous objections and rejections not set forth below have been withdrawn.

Information Disclosure Statement

An initialed and dated copy of Applicant's IDS form 1449, filed August 15, 2006 is attached to the instant Office action.

Claim Rejections - 35 USC § 112

Claim 35 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection. The recombinant expression vector of claim 35 requires a regulatory sequence that is not an Arabidopsis thaliana PP2A-4 promoter, which limitation does not find support in the specification as filed and thus constitutes new matter.

Art Unit: 1638

Claims 3-7, 15 and 19-20 remain rejected, and claims 17, 31-33 and 35 are rejected, under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in the office action mailed February 15, 2006.

Page 3

Applicant's arguments filed August 15, 2006 have been fully considered but they are not persuasive.

Applicant points out that the Examiner admits that no less than five different type 2A phosphatase polypeptides demonstrating 89-91% sequence identity and 93-94% sequence similarity to SEQ ID NO: 13 are disclosed in the application, and maintains that the facts Of *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997) are thus inapposite to the instant application, since the patent at issue in Lilly disclosed only a single cDNA species encoding rat insulin to support a claim to the genus of all cDNAs encoding mammalian insulin (reply page 15).

The Examiner maintains that the facts Of *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997) are apposite to the instant application, since the genus of sequences in the rejected claims do not encode type 2A phosphatase polypeptides; the genus of sequences in the rejected claims encode full-length polypeptides having "PP2A-4 activity". The Examiner maintains that the description of a single nucleotide sequence of SEQ ID NO:8 designated as PP2A-4 that encodes a single amino acid sequence of SEQ ID NO:13 that confers drought and cold stress tolerance when overexpressed in a plant does not support the description

Art Unit: 1638

of a genus of sequences that hybridize under stringent conditions to SEQ ID NO: 8, or that encode polypeptides having at least 90% sequence identity with SEQ ID NO:13.

Applicant also points to Lizotte DL et al. (Functional expression of human and *Arabidopsis* protein phosphatase 2A in *Saccharomyces cerevisiae* and isolation of dominant-defective mutants. Gene. 1999 Jun 24;234(1):35-44), which discloses at page 37, col. 1, that the amino acid sequences of PP2A serine/threonine phosphatase catalytic subunits "... are highly conserved in eukaryotes as distantly related as *Arabidopsis thaliana*, humans, and yeast.", and which further discloses that the *A. thaliana* PP2A gene is capable of complementing a conditional lethal yeast PP2A mutant, indicating that the function of PP2A is also conserved among eukaryotes. Applicant maintains that the correlation between structure and function of the PP2A serine/threonine phosphatase catalytic subunit was known at the priority date of the instant application, and maintains that, as a matter of law, therefore, the disclosure of five known PP2A species in the instant application adequately describes the genus of full-length polypeptides having PP2A-4 activity which can be transformed into plants to increase stress tolerance in accordance with the present claims. (reply page 16)

The Examiner maintains that neither Lizotte DL et al. nor the disclosure of five known PP2A species in the instant application adequately describes the genus of sequences in the rejected claims, as the genus of sequences in the rejected claims do not encode type 2A phosphatase polypeptides; the genus of sequences in the rejected claims encode full-length polypeptides having "PP2A-4 activity". In this regard it is noted that it is not established that "PP2A-4 activity" is the same as the activity exhibited by type 2A phosphatase polypeptides.

Art Unit: 1638

Claims 3-7, 15 and 19-20 remain rejected, and claims 17, 31-33 and 35 are rejected, under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a nucleic acid of SEQ ID NO:8 or a nucleotide sequence encoding SEQ ID NO:13, and for transgenic plants and plant cells transformed with a construct comprising a nucleic acid of SEQ ID NO:8 or a nucleotide sequence encoding SEQ ID NO:13 operably linked to a promoter in a sense orientation, and methods of making said plants and cells, does not reasonably provide enablement for other nucleic acid sequences, or for transgenic plants or plant cells transformed with other nucleic acid sequences. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, for the reasons of record set forth in the office action mailed February 15, 2006.

Applicant's arguments filed August 15, 2006 have been fully considered but they are not persuasive.

Applicant points to the Declaration Pursuant to 37 C.F.R. § 1.132 of Ruoying Chen, submitted herewith, which presents alignments of SEQ ID NO: 13 with the sequences of the five known PP2A homologs disclosed in Table 4 of the application. Applicant points out that the Declaration clearly shows that there is significant sequence similarity with the serine/threonine phosphatase family, including conservation of the serine/threonine phosphatase motif. Applicant maintains that contrary to the Examiner's position, the present application thus provides ample guidance to allow those of ordinary skill to make and to use the entire genus of serine/threonine phosphatase sequences in accordance with the presently claimed invention. Applicant also maintains that the yeast complementation assay of Lizotte et al. in fact provides an effective

Art Unit: 1638

functional assay to identify additional serine/threonine phosphatases suitable for transformation into plants to enhance stress tolerance. (reply page 17)

Page 6

The Examiner maintains that neither the Declaration nor Lizotte DL et al. provide sufficient guidance to enable the full scope of the claimed invention, as neither the Declaration nor Lizotte DL et al. provide specific guidance with respect to nucleic acid sequences that hybridize under stringent conditions to SEQ ID NO: 8 or that encode polypeptides having at least 90% sequence identity with SEQ ID NO:13 wherein the nucleic acid sequences encode full-length polypeptides having PP2A-4 activity and can be used to increase the tolerance of a plant cell transformed therewith to drought or cold stress. In this regard it is noted that the Declaration is silent with respect to the relevance, if any, of the Serine/Threonine phosphatase motif (LRGNHE) identified to the recited (encodes a full-length polypeptide having PP2A-4 activity) or disclosed (increases the tolerance of a plant cell transformed therewith to drought or cold stress) function of SEQ ID NO: 8. In this regard it is also noted that the genus of sequences in the rejected claims do not encode serine/threonine phosphatase polypeptides; the genus of sequences in the rejected claims encode full-length polypeptides having "PP2A-4 activity".

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3-4, 15, 17 and 35, and claims 5-7, 19-20 and 31-33 dependent thereon, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The

Art Unit: 1638

claims are indefinite in the recitation of "PP2A-4 activity". It is unclear what type of specific activity the encoded polypeptide exhibits, as "PP2A-4 activity" is neither defined in the specification nor known in the art.

Claims 17, 19, 31, 32 and 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are indefinite in the recitation of "stringent conditions". It is unclear what conditions would yield the claimed nucleic acid molecules, because those skilled in the art define "stringent conditions" differently. It is suggested that the claims be amended to recite specific hybridization conditions.

Allowable Subject Matter

Claims 1-2, 11-12 and 21-28 are allowed.

Claims 18 and 29-30 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Application/Control Number: 10/764,259 Page 8

Art Unit: 1638

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Remarks

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (571) 272-0794. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1638

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Cynthia Collins Primary Examiner Art Unit 1638 Page 9

CC

hydhia Cellins 10/25/06